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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 10/00	A1	(11) International Publication Number: WO 99/08601
		(43) International Publication Date: 25 February 1999 (25.02.99)

(21) International Application Number: PCT/NL98/00255

(22) International Filing Date: 6 May 1998 (06.05.98)

(30) Priority Data:
1005967 5 May 1997 (05.05.97) NL

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(81) Designated States: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
In English translation (filed in Dutch).

(54) Title: DIAGNOSTIC TESTING SYSTEMS

(57) Abstract

The present invention relates to a diagnostic testing system (1) with a support (2) provided with an adhesive layer (4) for attaching to the skin of a person to be tested and a protective layer (5) which is positioned on the adhesive layer. Test elements (8, 81) are arranged in flexible chambers of a packaging strip, which chambers may, if appropriate, be covered by a covering sheet (9). After removal of the covering sheet, the packaging strip can be placed on the support and the test elements can be applied to the support by pressing in the flexible chambers. The support can then be stuck, by means of the adhesive layer, to the skin of a person to be tested. The diagnostic testing system according to the present invention allows the support and the packaging strip to be supplied separately and allows the support, for example, to be produced, stored and transported on a roll. Furthermore, by means of the testing system according to the invention, there is considerable freedom in the number of test elements to be used, relatively little waste is produced and the test elements, after they have been applied to the support, can be protected against contamination by means of the packaging strip.

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Diagnostic testing system

The invention relates to a diagnostic testing system, comprising a support provided with an adhesive layer for attaching to the skin of a person to be tested and with a protective layer covering the adhesive layer, and a packaging strip, in which a number of chambers are formed, each with a peripheral wall which delimits a chamber opening and a flexible transverse wall situated opposite the opening, with a test element in each chamber, the peripheral wall being provided with retention means, which extend into the chamber, for retaining the respective test element in the chamber.

US-A-3,894,531 has disclosed a diagnostic testing system in which the chambers are formed in a flexible press-through strip. The chambers are provided with an opening which is delimited by a relatively narrow peripheral wall. A gauze containing a test substance is supported on the narrow peripheral wall. The chambers are covered by means of a covering sheet. After removal of the covering sheet, the chambers can be stuck to the skin of a patient and the gauze containing the test substance can be pressed onto the skin of the patient by pushing in the flexible transverse wall of the chambers. A system of this nature has the drawback that it can only be used with test substances which have been previously arranged in the chambers, so that the physician is unable to select the test substances him/herself. Also, the system is not flexible with regard to the number of test substances to be used.

Dutch patent application NL-A-9001667 has disclosed a diagnostic testing device with a number of relatively flat plastic test elements which are each provided with an absorbent material with a test substance therein. The test elements are arranged on a support which is made, for example, of a nonwoven fibre material. The support is provided with an adhesive agent which is covered by a protective strip with a number of openings through which the test elements pass. The test elements are covered by a removable covering strip. A system of this kind has the advantage that after the covering strip has been removed the physician can apply a test substance to the absorbent material of the test elements. However, if a relatively small number of test substances are to be used, the support has to be cut through and the unused test elements removed, which is a relatively laborious operation. Furthermore, after the covering strip has been removed, the absorbent material of the test chambers is exposed to possible contamination.

One object of the present invention is to provide a diagnostic testing system which allows considerable freedom with regard to the number of test substances to be used and in which the test elements can be effectively protected against possible contamination.

Another object of the invention is to provide a testing system in which there is no need to throw away test elements unused.

A further object of the present invention is to provide a diagnostic testing system which can be manufactured, transported and stored in a simple manner.

To this end, the diagnostic testing system according to the present invention is characterized in that the test elements comprise an attachment surface for attachment to the support and a diagnosis surface, which is situated opposite the attachment surface and comprises a test material, the diagnosis surface being directed towards the transverse wall of the chamber. In the testing system according to the invention, the packaging strip with the test elements therein and the support are supplied as separate units. In this case, the support may, for example, be stored on a roll, from which a section with the desired dimensions can be cut, or as separate plasters of a predetermined size. The roll with support material or the separate plasters may, for example, be accommodated in an automatic dispensing system.

The packaging strip may be designed without a covering sheet, in which case the test elements are retained in the chambers in a reliable manner by means of the retention means. If a covering sheet is used, the covering sheet can then be removed from the packaging strip, so that the chamber openings are exposed. After removal of the protective layer from the support, the packaging strip is placed over the support and, by pressing in the flexible transverse walls of the packaging strip, the attachment surfaces of the desired number of test elements are pushed onto the adhesive layer of the support. After removal of the packaging strip, a test substance can be applied to the diagnosis surfaces of the test elements, which face away from the support. However, it is also possible for a test substance to have been applied in advance to the absorbent test material of the diagnosis surfaces of the test elements.

Using the testing system according to the present invention provides a considerable freedom with regard to the number of test elements to be used. The system according to the invention is also efficient with regard to the number of test elements used: selecting to use a smaller number of test elements does not lead to surplus material

being thrown away. Furthermore, if a covering sheet over the packaging strips is used, the test elements are hermetically sealed in the packaging strip until the moment of use, so that they are sufficiently protected against contamination. Even after the test elements have been applied to the support and a test substance has been applied to the test elements, the packaging strip can be temporarily used as a cover and placed over the test elements, so that they are protected against contamination and so that evaporation of the test substance is prevented.

The test elements may be formed from a relatively stiff material, such as for example plastic. By pressing in the flexible transverse wall of the chambers in the packaging strip, the test elements can be pushed past the retention means, which consequently deform slightly. Preferably, the side walls of the test elements are of inclined design, so that when the test element is placed in the plane of the opening of a chamber the test element is released by the retention means and remains on the support after the packaging strip has been removed.

Preferably, the protective layer of the support is provided with openings, the shape and respective positions of which correspond to the chambers of the packaging strip. These openings are covered by a second protective layer. After removal of this second protective layer, only that part of the adhesive agent of the support which corresponds to the positions of the test elements which are to be applied to the support is released. After these test elements have been pressed out of the packaging strip, the result is a test plaster which is easy to handle, for example in order to apply a test liquid to the test elements. Then, the protective layer comprising the openings can be removed from the support, so that the adhesive agent of the support is released further so as to be applied to the skin of a patient.

In order to facilitate positioning the packaging strip with respect to the support, the peripheral walls of the chambers in the packaging strip project, in the region of the openings, beyond the plane of the connecting parts situated between the chambers over a distance which is at least equal to the thickness of the first protective layer of the support. As a result, a positioning edge, or a number of positioning projections, is formed along the opening of the chambers, which positioning edge or positioning projections can engage through the openings in the first protective layer of the support and help with positioning the packaging strip above the openings in the protective layer of the support.

In one embodiment, the chambers are sealed off by a covering sheet which is attached only along a continuous contour. As a result, the test elements are enclosed in the chambers in a simple manner without the need to use an adhesive agent. As a result, the risk of the test elements being contaminated by an adhesive agent of this nature is minimized.

Preferably, a sheet of absorbent material is applied to the diagnosis surface of the plastic test elements, such as for example a filter paper which is arranged in the mould when the test elements are being injection moulded and is moulded in and which extends as far as beneath the upright side edge of the test elements. This prevents the absorbent material from coming off the diagnosis surface when a test liquid is applied thereto.

Preferably, the support is provided with a central strip for attaching the test elements to the support and with a writing strip on either side thereof, in which case the protective layer is cut through between the central strip and the writing strip. In this way, it is possible to indicate on the writing strip which test material is on which test element, and this writing strip can remain present when the prepared test plaster is applied to the skin.

An embodiment of a testing system according to the present invention will be explained in more detail, by way of example, with reference to the appended drawing, in which:

Figure 1 shows a diagrammatic, perspective view of a testing system according to the present invention,

Figure 2 shows a cross-section through the testing system of Figure 1 on a line II-II as shown in Figure 1,

Figure 3 shows a prepared test plaster after the test elements have been applied to the support,

Figure 4 shows a perspective view of a support strip according to the present invention,

Figures 5 and 6 show respective embodiments of a continuous web of support material according to the present invention, and

Figure 7 shows a preferred test element according to the present invention.

Figure 1 shows a perspective view of a diagnostic testing system 1 with a support 2 and a packaging strip 3. The support 2 is provided with an adhesive layer 4 with an adhesive agent, which is covered by a first protective layer 5. The packaging strip 3 comprises a number of chambers 6,7 in which test elements 8,8' are accommodated. In

the embodiment shown, the chambers 6,7 are covered by a covering sheet 9 which is attached along a continuous contour 10, for example by fusion welding, to the sheet comprising the chambers 6,7. The diagnosis surface of the test elements 8,8' is directed towards the transverse wall of the chambers 6,7 and the attachment surface thereof is directed towards the covering sheet 9. As can be seen from Figure 2, which shows a diagonal section through a chamber on line II-II in Figure 1, each chamber comprises a flexible transverse wall 12 and a peripheral wall 13. In the region of the opening of the chamber, the peripheral wall 13 is provided with retention means in the form of projections 14,15. On the side of its attachment surface 16, the test element 8' is supported on the projections 14,15, and is consequently held in the chamber even after the covering sheet 9 has been removed. The side wall 18 of the test element 8' is of inclined design, so that it is wider in the region of the attachment surface 16 than in the region of the diagnosis surface 17 of the test element 8'. By pressing in the flexible transverse wall 12, the projections 14,15 of the peripheral wall 13 are deformed by the test element 8' and the attachment surface 16 is pushed onto the adhesive layer 4 of the support. As a result of the inclined side walls 18, the test element 8' is released from the chamber as soon as its widest part, which is situated in the region of the attachment surface 16, has moved past the projections 14,15.

To allow correct positioning of the packaging strip 3 with respect to the support 2, the side wall 13 is provided with a positioning edge or positioning projections 19,20 which can be supported on the adhesive layer 4. The positioning projections 19,20, which, when the packaging strip 3 is being placed on the support 4, bear against the side edges of the openings 26,26' in the protective layer 5, provide accurate orientation of the chambers 6,7 with respect to the openings 26,26' in the first protective layer 5.

After the test elements 8,8' have been pressed out of the chambers 6,7 of the packaging strip 3, the testing system is ready for use, as shown in Figure 3. For this purpose, a physician can apply a test liquid to the diagnosis surfaces of the test elements 8,8'. Then, the central strips 22,22' of the first protective layer 5 can be removed, so that the adhesive agent of the adhesive layer 4 is uncovered. At the location of writing strips 23,23', the first protective layer 5 remains on the adhesive layer. At least for the writing strips 23,23', the material of the first protective layer 5 is such that it can be written

on using, for example, a ballpoint pen or felt-tip pen. When placing the prepared support, with the test elements 8,8' on it, onto the skin of a patient, the first protective layer 5 remains in place at the location of the writing strips 23,23'.

Figure 4 shows a support which is suitable for use in the diagnostic testing system according to the present invention, with the openings 26,26' in the first protective layer 5 covered by a second protective layer 24. Separate writing strips 23,23' of the first protective layer extend on either side of the central part.

As shown in Figure 5, the support may comprise a continuous web 25 of connected supports which are joined together via perforation lines 31. A web 25 of this nature can be supplied on a roll and may, for example, be arranged in a dispensing system for automatically dispensing a single support plaster while simultaneously removing the second protective layer 24 via, for example, a machine.

Figure 6 shows an alternative embodiment of a support according to the present invention, in which central strips 27,27' are provided for attaching the test elements. An adhesive strip 28,29;28',29' for attaching to the skin of a patient is situated on either side of the central strips 27,27'. Each outer adhesive strip 28,28' adjoins a writing strip 30,30'. Using the adhesive strips 28,29,28',29' which extend along the test elements in the longitudinal direction results in good adhesion to the skin of a patient.

Finally, Figure 7 shows a lateral cross-section through a test element 32 according to the present invention which is formed by injection-moulding. During the injection-moulding, an absorbent element 35, such as an absorbent paper, is placed in the mould and is simultaneously moulded into the test element 32 at the location of the diagnosis surface 38. In this case, a peripheral edge 36 of the test paper 35 extends as far as beneath the upright edge 34 of the side wall 33, which edge is situated opposite to the attachment surface 37.

Although the invention has been described with reference to test elements 8,8' which are placed separately in the packaging strip 3, this invention is also suitable for test elements 8,8' which are connected together by means of a casting. To this end, passages may be arranged in the packaging strip, which passages connect the chambers 6,7 together and in which passages the casting can be accommodated.

The diagnostic testing system according to the present invention may also advantageously be used with pre-prepared test

elements, in which the test substance is already present in the chambers 6,7, which have been closed off by means of the covering sheet 9, of the packaging strip 3.

In yet another embodiment of a diagnostic testing system according to the invention, the covering sheet 9 may be omitted entirely and the test elements are retained in the chambers only by the clamping action of the projections 14,15. In this case, the packaging strips will have to be handled more carefully in order to prevent contamination of the test elements than if a covering sheet were to be used.

CLAIMS

1. Diagnostic testing system (1), comprising

- a support (2) provided with an adhesive layer (4) for attaching to the skin of a person to be tested and with a protective layer (5,24) covering the adhesive layer, and

- a packaging strip (3), in which a number of chambers (6,7) are formed, each with a peripheral wall (13) which delimits a chamber opening and a flexible transverse wall (12) situated opposite the opening, with a test element (8,8',32) in each chamber, the peripheral wall (13) being provided with retention means (14,15), which extend into the chamber, for retaining the respective test element (8,8',32) in the chamber,

characterized in that the test elements (8,8',32) comprise an attachment surface (16,37) for attachment to the support (2) and a diagnosis surface (17,38), which is situated opposite the attachment surface (16,37) and comprises a test material (35), the diagnosis surface (17,38) being directed towards the transverse wall (12) of the respective chamber.

2. Diagnostic testing system (1) according to Claim 1, characterized in that the test elements (8,8',32) are formed from a relatively stiff material, in which case the test elements can be displaced in the chambers by pressing in the transverse wall (12) and can be moved past the retention means (14,15) and into the plane of the opening of the chambers, the test elements (8,8',32) being released by the retention means (14,15) in that position.

3. Diagnostic testing system (1) according to Claim 2, characterized in that the test elements (8,8',32) are provided with a wall (18,33), the distance between mutually opposite parts of the side wall (18,33) in the region of the adhesive surface (16,37) being greater than the distance between the mutually opposite parts of the side wall (18,33) in the region of the diagnosis surface (17,37).

4. Diagnostic testing system (1) according to one of the preceding claims, characterized in that the protective layer (5) of the support (2) is provided with openings (26,26'), the shape and respective positions of which correspond to the chambers (6,7) of the packaging strip (3), the openings (26,26') being covered by a second protective layer (24).

5. Diagnostic testing system (1) according to Claim 4, characterized in that the packaging strip (3) is provided, between the chambers (6,7), with virtually planar connecting parts, the peripheral walls (13) of the chambers (6,7) projecting, in the region of the chamber

openings, beyond the plane of the connecting parts, over a distance which is at least equal to the thickness of the first protective layer (5) of the support (2).

6. Diagnostic testing system according to one of the preceding claims, characterized in that the chamber openings are covered by a removable covering sheet (9).

7. Diagnostic testing system (1) according to Claim 6, characterized in that the covering sheet (9) is attached to the layer comprising the chambers only along a continuous contour (10).

8. Diagnostic testing system (1) according to one of the preceding claims, characterized in that the test elements (32) comprise a plastic plate with an upright side edge (34) on the side of the diagnosis surface (38) and, as test material, a sheet of absorbent material (35) which is attached to the diagnosis surface (38) and the peripheral edge (36) of which extends as far as beneath the upright side edge (34) of the test element (32).

9. Diagnostic testing system (1) according to one of the preceding claims, characterized in that the support (2) is provided with a central strip (22,22',27,27') for attaching the test elements, and with a writing strip (23,23',30,30') on either side of the central strip (22,22',27,27'), the first protective layer (5) being cut through between the central strip (22,22',27,27') and the writing strips (23,23',30,30').

10. Diagnostic testing system (1) according to Claim 9, characterized in that an adhesive strip (28,29;28',29') for attaching to the skin of the person to be tested is provided on either side of the central strip (27,27'), the protective layer (5) being cut through between the central strip (27,27') and the adhesive strips.

11. Diagnostic testing system (1) according to one of the preceding claims, characterized in that the test elements (8,8',32) in the chambers (6,7) are provided with a test substance.

12. Packaging strip for use in a diagnostic testing system according to one of the preceding claims, with a number of chambers (6,7) formed therein, each with a peripheral wall (13) which delimits a chamber opening and a flexible transverse wall (12) situated opposite the opening, with a test element (8,8',32) in each chamber, the peripheral wall (13) being provided with retention means (14,15), which extend into the chamber, for retaining the respective test element (8,8',32) in the chamber, characterized in that the test elements (8,8',32) comprise an attachment surface (16,37) for attachment to the support (2) and a

diagnosis surface (17,38), which is situated opposite the adhesive surface (16,37) and comprises a test material (35), the diagnosis surface (17,38) being directed towards the transverse wall (12) of the respective chamber.

13. Packaging strip according to Claim 11, characterized in that the test elements (8,8',32) are formed from a relatively stiff material, in which case the test elements can be displaced in the chambers by pressing in the transverse wall (12) and can be moved past the retention means (14,15) and into the plane of the opening of the chambers, the test elements (8,8',32) being released by the retention means (14,15) in that position.

14. Packaging strips according to Claim 12 or 13, characterized in that the chamber openings are covered by a removable covering sheet (9).

15. Support for use in a diagnostic testing system according to one of Claims 1 to 11, characterized in that the protective layer (5) of the support (2) is provided with openings (26,26'), the shape and respective positions of which correspond to the chambers (6,7) of the packaging strip (3), the openings (26,26') being covered by a second protective layer (24).

16. Support according to Claim 15, characterized in that the support (2) is provided with a central strip (22,22',27,27') for attaching the test elements, and with a writing strip (23,23',30,30') on either side of the central strip (22,22',27,27'), the first protective layer (5) being cut through between the central strip (22,22',27,27') and the writing strips (23,23',30,30').

17. Support according to Claim 15 or 16, characterized in that an adhesive strip (28,29;28',29') for attaching to the skin of the person to be tested is provided on either side of the central strip (27,27'), the protective layer (5) being cut through between the central strip (27,27') and the adhesive strips.

18. Test element (8,8',32) for use in a testing system according to one of Claims 1 to 11, characterized in that the test elements are provided with a wall (18,33), the distance between mutually opposite parts of the side wall (18,33) in the region of the attachment surface (16,37) being greater than the distance between the mutually opposite parts of the side wall (18,33) in the region of the diagnosis surface (17,37).

19. Test element for use in a testing system according to one of Claims 1 to 11, characterized in that the test elements (32) comprise a

plastic plate with an upright side edge (34) on the side of the diagnosis surface (38) and, as test material, a sheet of absorbent material (35) which is attached to the diagnosis surface (38) and the peripheral edge (36) of which extends as far as beneath the upright side edge (34) of the test element (32).

Fig-1

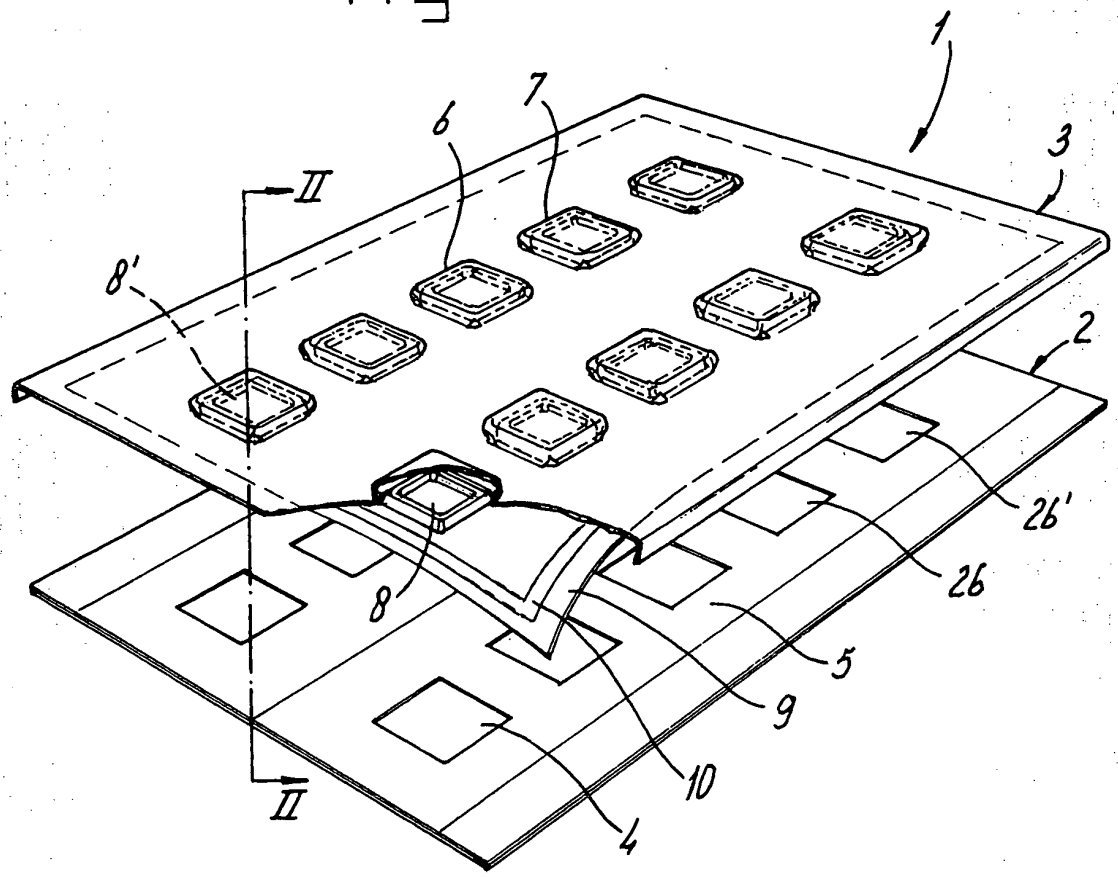


Fig-2

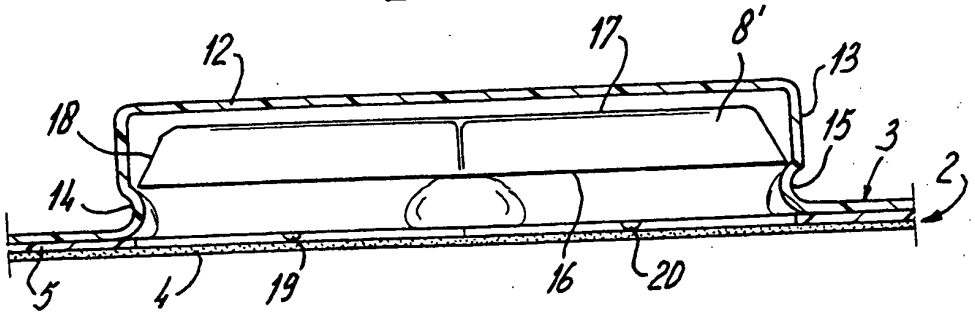


Fig - 3

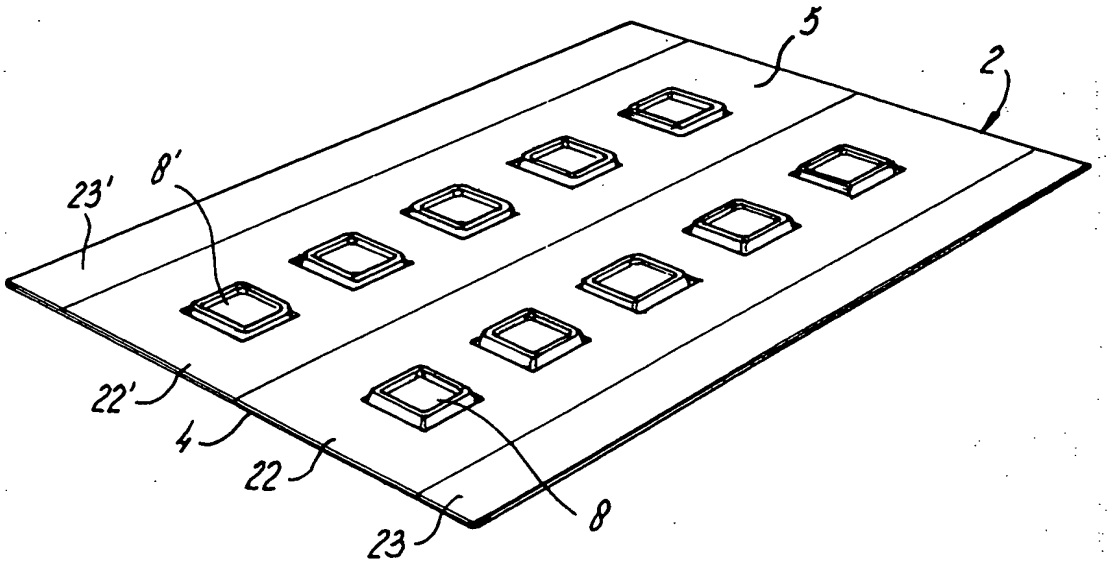


Fig - 4

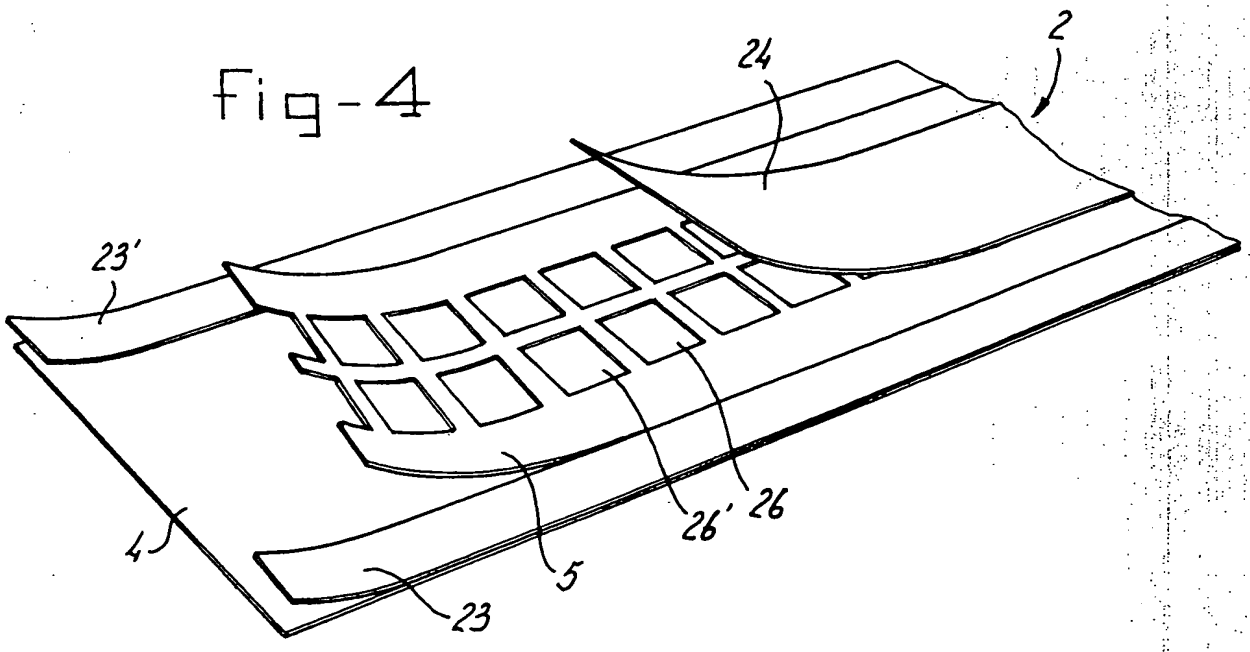


Fig-5

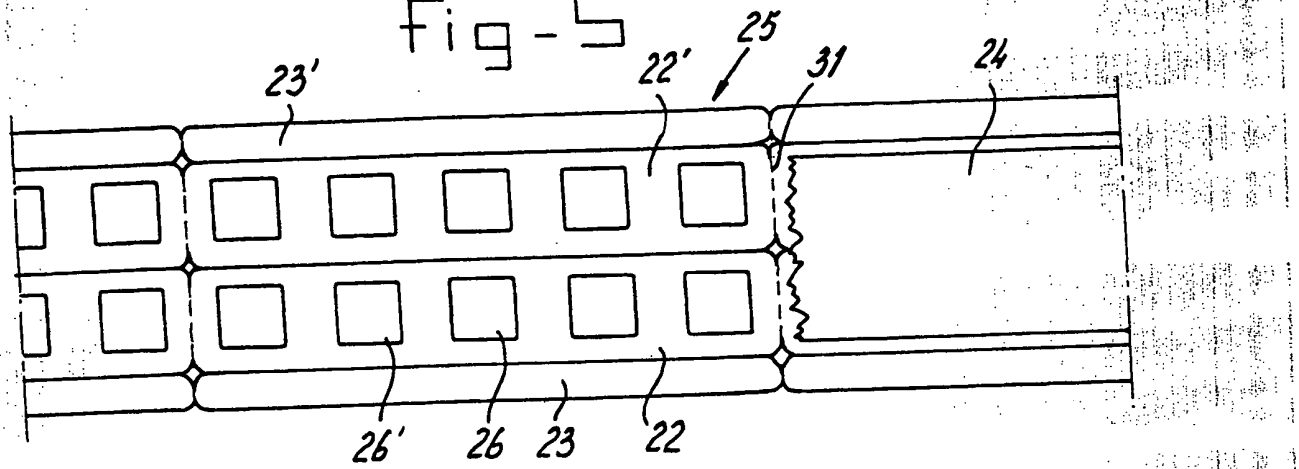


Fig-6

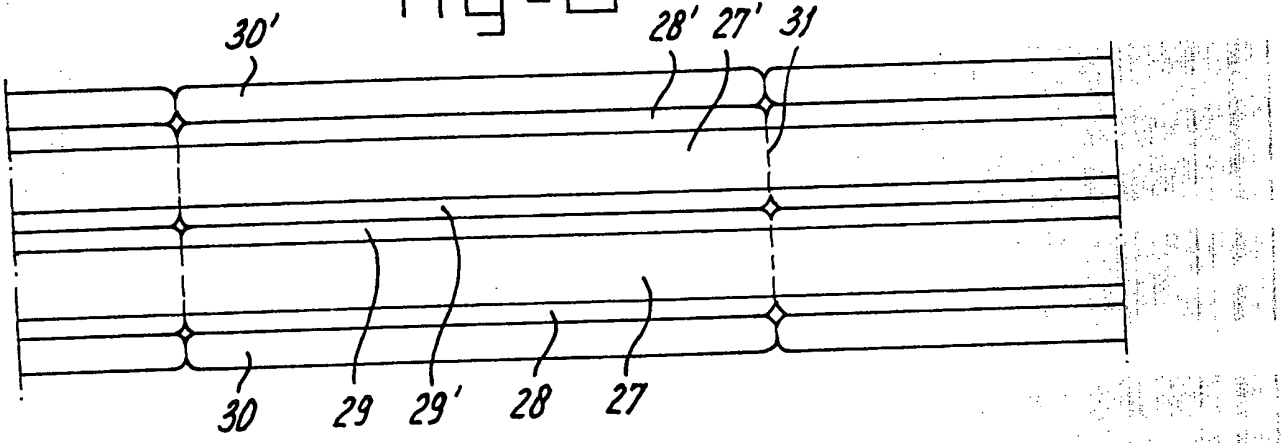
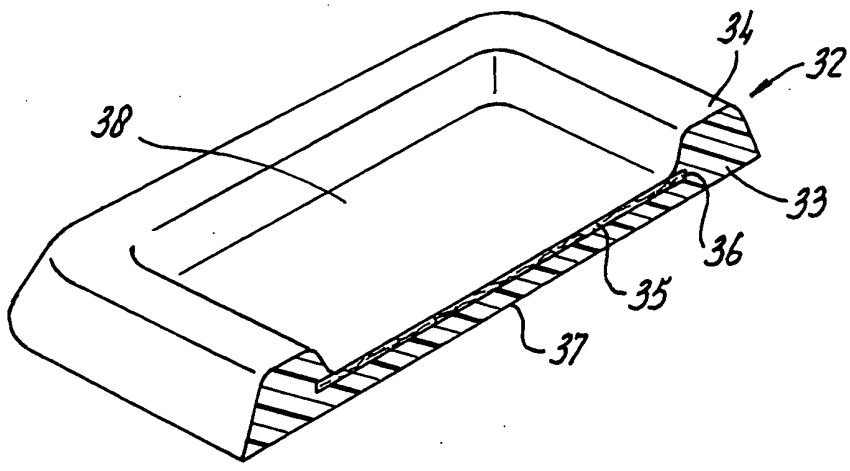


Fig-7



INTERNATIONAL SEARCH REPORT

International Application No
PCT/NL 98/00255

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B10/00

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 390 027 A (ALANI ET AL.) 28 June 1983 see column 6, line 48 - line 55	1,12,15, 18,19
A	US 4 788 971 A (QUISNO) 6 December 1988 see column 5, line 16 - line 31 see column 7, line 11 - line 27	1,12,15, 18,19
A	DE 94 00 844 U (SIEWERT) 31 March 1994	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of theinternational search	Date of mailing of the international search report
25 August 1998	01/09/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Glas, J

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Information on patent family members

Int ional Application No
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